



Due Date: January 5, 2001

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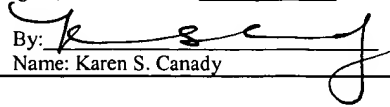
Applicant: Daniel E. Afar et al. Examiner: M. Davis  
Serial No.: 09/389,000 Group Art Unit: 1642  
Filed: August 31, 1999 Docket: G&C 129.27-US-U2  
Title: PHELIX: A TESTIS-SPECIFIC PROTEIN EXPRESSED IN CANCER

JAN 12 2001

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By:   
Name: Karen S. Canady

BOX NON-FEE AMENDMENT  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

We are transmitting herewith the attached:

- ☒ Transmittal sheet, in duplicate, containing a Certificate of Mailing under 37 CFR 1.8.
- ☒ Response to Restriction Requirement.
- ☒ Return postcard.

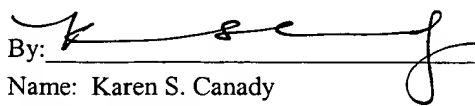
CLAIMS PRESENT

Claims Remaining:	Highest Number Previously Paid For:	Number Extra	Rate	Fee
Total Claims				
53	53	0	x \$18.00	= \$0.00
Independent Claims				
36	36	0	x \$80.00	= \$0.00
MULTIPLE DEPENDENT CLAIM FEE				\$0.00
TOTAL FILING FEE				\$0.00

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate.

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**GATES & COOPER**  
Howard Hughes Center  
6701 Center Drive West, Suite 1050  
Los Angeles, CA 90045  
(310) 641-8797

By:   
Name: Karen S. Canady  
Reg. No.: 39,927  
KSC/amb

(PTO TRANSMITTAL - GENERAL)



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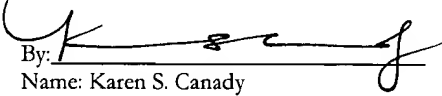
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By:   
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RESPONSE TO RESTRICTION REQUIREMENT

BOX NON-FEE AMENDMENT  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

This communication is submitted in response to the Office Action dated December 5, 2000.

REMARKS

The Office Action dated December 5, 2000 requires restriction of the claims into 16 claim Groups. In addition, the Office Action requires a further election of species within each of Groups II, III, VII, X, XI, XII, XIII, XIV, XV and XVI. In response, Applicants elect Group I, claims 1-4, 13, 51 and 52, drawn to PHELIX proteins, with traverse. Applicants maintain that the 16 claim groups do not involve independent and distinct inventions.

35 U.S.C. §121 provides that "If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." M.P.E.P. §802.01 deviates from the plain meaning of "independent and distinct" by interpreting "and" to mean "or". The Patent Office relies on the absence from the legislative

history of anything contrary to this interpretation as support for their position that “and” means “or”. Applicants respectfully note that this position is contrary to the rules of statutory construction. Restriction between two dependent inventions is not permissible under the plain meaning of 35 U.S.C. §121.

The Examiner does not assert that the inventions of the 16 claim groups are independent. Rather, the Examiner alleges that the inventions of the 16 claim groups are distinct because they are directed to products and process of use, or to products having different structures, biological properties and activities that are not interchangeable and/or cannot be used in place of each other or together, or to methods differing in their objectives, steps, parameters and reagents used. Likewise, the Examiner asserts that the various species subject to election are distinct because they are structurally distinct or because the different cancers have different characteristics and etiology. By this reasoning, however, any two claims would either relate to distinct inventions or be duplicative, depending on whether they defined subject matter having distinct structural and functional characteristics.

Applicants assert that restriction is improper because separate significant search efforts should not be necessary to examine Groups 1-16 of the subject application. Applicants further urge the Examiner take into consideration that the subject matter of each of the claim groups is linked by a common inventive concept. As noted in the specification at page 4, lines 16-28, the invention relates to a novel gene and protein, designated PHELIX, that is normally expressed only in testis, but is expressed at high levels in advanced and metastatic prostate cancer as well as in other types of cancer. This inventive concept is common to all of the subject matter of claims 1-53. Even if the subject matter of Groups 1-16 are regarded as distinct, it is not clear how separate significant search efforts would be required to evaluate the patentability of all claims relating to a single novel molecule. At the very least, a search of the art relating to Groups I, III, V and VII, all of which relate to the novel PHELIX protein and antibodies directed against PHELIX, could be completed with a single search effort directed at the protein, and rejoinder of these groups for examination is respectfully requested.

According to M.P.E.P. §803, there are two criteria for a proper restriction requirement. First, the two inventions must be independent and distinct. In addition, there must be a serious burden on the Examiner if restriction is not required. Even if the first criterion has been met in the present case, which it has not, the second criterion has not been met.

Applicants assert that a search into prior art with regard to the invention of the different groups is so related that separate significant search efforts should not be necessary. Accordingly, there is no serious burden on the Examiner to collectively examine the different claim groups of the subject application. Therefore, restriction is not proper under M.P.E.P. §803.

Consequently, Applicants respectfully request the Examiner reconsider and withdraw the restriction requirement. It is also submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

Daniel E. Afar et al.

By their attorneys,

GATES & COOPER

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(310) 641-8797

Date: January 4, 2001

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